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Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/736,890 01/03/00 CUNNINGHAM

I 09/10/01

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HM12/0912

EXAMINER
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NGUYEN, L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/706,580

Applicant(s)

CUNNINGHAM, JANET

Examiner

Lauren Nguyen

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-29 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**KATRINA TURNER**  
**PATENT ANALYST**

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to a recombinant AAV virion comprising a promoter operably linked to a polynucleotide of interest comprising at least one ecdysone-responsive element downstream of at least one ecdysone-responsive element, classified in class 435, subclass 320.1, for example.
  - II. Claims 11-18, drawn to a recombinant AAV virion comprising a first coding sequence encoding an ecdysone receptor, classified in class 435, subclass 320.1, for example.
  - III. Claims 19 and 20, drawn to a method of producing recombinant AAV virions comprising transfecting a host cell with an AAV vector comprising a transcriptional promoter comprising at least one ecdysone-responsive element, classified in class 435, subclass 70.1, for example.
  - IV. Claims 21-23, drawn to a method of producing recombinant AAV virions comprising transfecting a host cell with an AAV vector comprising a first coding sequence encoding an ecdysone receptor, classified in class 435, subclass 70.1, for example.
  - V. Claims 24-29, drawn to a method of inducing gene expression in a mammalian cell comprising transducing said cell with a first recombinant AAV virion

comprising an AAV vector comprising a promoter comprising at least one ecdysone-responsive element, classified in class 435, subclass 455, for example.

These inventions are distinct, each from the other, for the following reasons:

Inventions III and IV are related to inventions I and II as process of making and product made, respectively. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed in Groups I and II can be made by processes other than those claimed in Group III and IV. For instance, the recombinant AAV virions claimed in Groups I and II can be made by synthetically packaging a synthetically produced AAV vector, for example.

Inventions I and II are related to invention V as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Groups I and II can be used in a process other than that claimed in Group V. For instance, the recombinant AAV virions claimed in Groups I and II can be used as vehicles for nucleic acid packaging, for example.

Invention I, drawn to a recombinant AAV virion comprising a promoter operably linked to a polynucleotide of interest comprising at least one ecdysone-responsive element, is distinct

from invention II, drawn to a recombinant AAV virion comprising a first coding sequence encoding an ecdysone receptor. Groups I and II are drawn to materially different products since a responsive element, as claimed in Group I, can read on transcription factors, for instance, which has different and distinct biological properties from a receptor. Moreover, said transcription factor could, for instance, have a different and unique chemical identity from that of the receptor and would thereby necessitate a new field of search.

Groups III, IV, and V are distinct, each from the other, because each invention is drawn to materially different processes involving materially different steps with materially different products. A method of producing recombinant AAV virions, as claimed in Groups III and IV, is materially different from a method of inducing gene expression in a mammalian cell, as claimed in Group V, because a method of inducing gene expression includes additional considerations, such as transfection efficiencies and genomic integration for instance, which would necessitate a new field of search from the methods claimed in Group III and IV. The methods claimed in Groups III and IV are distinct from each other because each process involves materially different products. A recombinant AAV virion comprising an ecdysone-responsive element, as practiced in the method as claimed in Group III, is materially different from a recombinant AAV virion comprising an ecdysone receptor, as practiced in the method as claimed in Group IV, because a responsive element can read on transcription factors, for instance, which has different and distinct biological properties from a receptor. Moreover, said transcription factor could, for instance, have a different and unique chemical identity from that of the receptor and thereby necessitating a new field of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

A telephone call was made to Roberta Robins on 15 August, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Nguyen, Ph.D. whose telephone number is 703-308-0256. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-7939 for After Final communications.

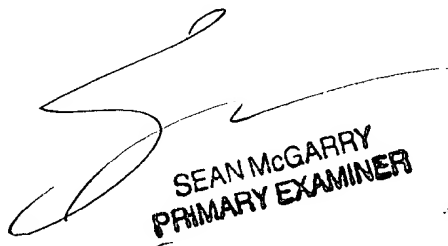
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lauren Nguyen, Ph.D.  
August 30, 2001



SEAN MCGARRY  
PRIMARY EXAMINER